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## **GENFIT ANNOUNCES THE IMPLEMENTATION OF TWO GROUPS OF EXPERTS DEDICATED TO THE FUTURE DEVELOPMENT OF GFT505 IN NAFLD/NASH**

- **Discussions on the design of a Phase IIb study have been initiated with the EMA.**

**Lille (France), Cambridge (Massachusetts, United States), October 24, 2011** – GENFIT (Alternext: ALGFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of drug discovery and development, focusing on the early diagnosis and preventive treatment of cardiometabolic and associated disorders, today announces the organization of two groups of experts for future clinical studies of GFT505 in NAFLD/NASH.

Based on the positive clinical results obtained with GFT505 in studies demonstrating efficacy in different patient populations, and on clinical objectives of NASH, GENFIT has put in place a dedicated advisory board (SAB-505-NAFLD/NASH), comprised of the best international experts (United States, United Kingdom, France, and Italy).

Among the experts are hepatologists, diabetologists, cardiologists, lipidologists, and pathologists, who are renowned for their work in NASH, totaling over 1000 scientific publications. Members of prestigious high impact scientific societies (IAS, EASL, AASL, ADA, EASD, NASH-CRN of NIH), these experts are principal investigators of some of the largest major clinical studies conducted to date in NASH. The advisory board will assist GENFIT in the set-up of the pivotal Phase IIb trial, and advise the company on the development plan up to NDA approval, in concertation with the regulatory agencies (EMA and FDA).

For this purpose, GENFIT has initiated discussions with the EMA to precisely define the study designs of the pivotal Phase IIb and Phase III trials required for NDA approval in NASH.

In parallel, with the objective to anticipate the regulatory requirements in pharmacovigilance and safety, GENFIT also announces the implementation of a Data and Safety Monitoring Board (DSMB), which will be responsible for evaluating and adjudicating the safety of the product throughout the Phase IIb and Phase III development. This international DSMB is composed of cardiologists, hepatologists, and methodologists independent of the NAFLD/NASH advisory board, and their decisions will be taken totally independent of the study sponsor.

**Jean-François Mouney, CEO & Chairman of GENFIT's Management Board, declared:** *“By involving the best experts in the field of NASH and drug development, GENFIT is structuring its organization to optimize the Phase IIb and Phase III of GFT505. By doing so, GENFIT is assuring the perfect accordance between the development plan of the product and the requirements of the regulatory agencies up to NDA approval, both in terms of efficacy and safety of use.”*

### **About GENFIT:**

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in therapeutic fields linked to cardiometabolic disorders (prediabetes/diabetes, atherosclerosis, dyslipidemia, inflammatory diseases...). GENFIT uses a multi-pronged approach based on early diagnosis, preventive

solutions, and therapeutic treatments and advances therapeutic research programs, either independently or in partnership with leading pharmaceutical companies (SANOFI, SERVIER, ...), to address these major public health concerns and their unmet medical needs.

GENFIT's research programs have resulted in the creation of a rich and diversified pipeline of drug candidates at different stages of development, including GENFIT's lead proprietary compound, GFT505, that is currently in Phase II.

With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 100 employees. GENFIT is a public company listed on the Alternext trading market by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111). [www.genfit.com](http://www.genfit.com)

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